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News and Issues for Washington's Clinical Laboratories

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New Calibration Verification Requirements

by Leonard Kargacin, DOH LQA

New revisions to the MTS/CLIA rules include requirements for calibration verification on both moderate and high complexity test systems. This article, based on a document from the Centers for Medicare & Medicaid Services, will review calibration and the new requirements for calibration verification in a question and answer format.

Calibration is the process of testing and adjusting an instrument, kit, or test system readout to establish a correlation between the instrument's measurement of the substance being tested and the actual concentration of the substance.

Q: Is there a new requirement for calibration?
A: No, the MTS/CLIA requirements for calibration have not changed. The laboratory is responsible for performing calibration as directed by the manufacturer's test system instructions, and when calibration verification of the test system (see below) does not produce acceptable results.

Q: Is calibration required for every procedure my laboratory performs?
A: No, calibration is not required for the following:

- Manual procedures such as microbiology cultures, and tilt-tube prothrombin time test systems.
- Microscopic procedures such as KOH preparations, pinworm preparations, urine sediment analysis, all manual cell differential procedures, and manual cytology screening procedures.
- Procedures involving an instrument in which calibration is not practical such as timed coagulation procedures (protime, PTT, ACT).

Q: How do I perform calibration?
A: The test system's instructions should describe the process for performing calibration, as well as when and how often it is to be performed.

Q: What materials should I use to perform calibration?
A: The test system's instructions should specify the number, type, and concentration of the calibration material to use. Calibration material is a solution or lyophilized preparation that contains a known concentration of the analyte of interest.

NOTE: Be sure to keep the written documentation each time you perform a calibration.

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia
ANA
Bioterrorism Event Mgmt
Bleeding Disorders
Chlamydia
Diabetes
Group A Strep Pharyngitis
Hepatitis
HIV
Infectious Diarrhea
Intestinal Parasites
Lipid Screening
PAP Smear
Point-of-Care Testing
PSA
Rash Illness
Red Cell Transfusion
Renal Disease
STD
Thyroid
Tuberculosis
Urinalysis
Wellness

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Calibration verification means the testing of materials of known concentration in the same manner as patient samples to assure the test system is accurately measuring samples **throughout the reportable range**.

Q: Is there a new requirement for calibration verification?

A: Yes, for moderate complexity testing; No, for high complexity testing. The process for calibration verification has always been defined for high complexity test systems. However, the process for calibration verification of moderate complexity test systems was not defined. The regulations now describe how and when calibration verification is to be performed for non-waived (moderate and high complexity) tests.

Q: When must I perform calibration verification?

A: Once every 6 months (or more frequently if specified in the test system's instructions) and whenever any of the following occur:

- All of the reagents used for a test procedure are changed to new lot numbers, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results and control values are not adversely affected by reagent lot number changes.
- There is a major preventive maintenance or replacement of critical parts that may influence the test's performance. This includes when the laboratory sends a test system to the manufacturer for repairs. The laboratory must check the calibration of a repaired test system before resuming patient testing and reporting results.
- Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
- The laboratory has determined that the test system's reportable range for patient test results should be checked more frequently.

NOTE: The laboratory is responsible for verifying calibration on factory-calibrated test systems that cannot be calibrated by the user.

Q: What materials should I use to perform calibration verification?

A: A variety of materials with known concentrations may be used to verify calibration. Here are some examples: proficiency testing samples with known values; patient specimens with known values; or commercially available standards, calibration materials, or control materials with known values as long as they are not the same lot number as those in current use.

Since the purpose of calibration verification is to check whether the test system is providing accurate results throughout the reportable range, three levels should be tested (one at the high end of the reportable range, one at the low end of the reportable range, and one near the midpoint of the reportable range).

NOTE: Be sure to keep the written documentation each time you perform calibration verification.

Q: Are there exceptions to calibration verification requirements?

A: Yes, there are exceptions:

- Control activities routinely used to satisfy the daily QC requirements do not satisfy the calibration verification requirements. However, there is an exception for automated cell counters. For automated cell counters, the calibration verification requirements are considered met if the

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LQA home page: http://www.doh.wa.gov/lqa.htm
PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

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laboratory follows the manufacturer's instructions for instrument operation, and tests two levels of control material each day of testing, provided the control results meet the laboratory's criteria for acceptability.

NOTE: At the time of installation of your hematology analyzer, it is recommended that linearity standards be tested that challenge the stated reportable range of the instrument. This is especially important in oncology practices where patient samples routinely challenge the low and upper limits of the instrument.

- If the test system's calibration procedure includes three or more levels of calibration material, **and** includes a low, mid, and high value, **and** is performed at least once every six months, then the requirement for calibration verification is also met.

Q: What should I do if calibration verification fails?
A: If calibration verification results are unacceptable, you must repeat the test system's calibration procedure. After repeating the calibration procedure, it is good laboratory practice to run controls before resuming patient testing.

If the instrument is factory calibrated, consult with the manufacturer of the test system.

Q: When should I implement calibration verification?
A: The revised MTS Rules were effective on 3-19-05, so calibration verification should be implemented for the applicable test systems in your laboratory within six months of that date. LQA surveyors will expect to see that progress is being made to implement the new requirements during your next on-site inspection. For the next 2-year inspection cycle, LQA surveyors will be educating personnel about the new requirements and writing recommendations for implementation.

Where do I start? Here are some tips:

- Review the manufacturer's instructions to see if the calibration and calibration verification protocols are described for your test system.
- Call your instrument manufacturer's technical representative and ask how to do calibration verification to meet the requirement.
- Call your instrument manufacturer's technical representative for suggestions on what materials they recommend for your particular test system.
- Locate sources of material to use for calibration verification such as:
  - Commercially available standards or calibration material.
  - Proficiency testing samples with known values.
  - Patient specimens with known values.
  - Control materials (a different lot number from the material you are currently using for QC) with known values.

NOTE: Since the purpose of calibration verification is to check whether the test system is providing accurate results throughout the reportable range, three levels should be tested (one at the high end of the reportable range, one at the low end of the reportable range, and one near the midpoint of the reportable range).

Additional information about the MTS/CLIA requirements pertaining to calibration and calibration verification can be found at the following websites:

Refer to Table 090-2 in the MTS WAC available at the LQA website, **http://www.doh.wa.gov/lqa.htm**. (Select *Updates;* Select *Revised Medical Test Site Rules*)

Refer to "The State Operations Manual," Appendix C – Interpretive Guidelines, Calibration and Calibration Verification Procedures (493.1255) available at the CMS website at **http://www.cms.hhs.gov/clia**.

TIPS for Proficiency Testing Success

Improve your chances for successful participation in PT by implementing the following suggestions:

Retain all raw data: Save data showing the workup of PT samples, instrument printouts, worksheets, log sheets.

Fill in the Method Code: Do not leave blank.

Correctly report the reason PT was not done: If you are unable to test for some reason, indicate this on the answer sheet. If you discontinued testing for an analyte, indicate this on the sheet. Immediately notify LQA of any change.

Be timely: Always be sure to meet the deadline for returning your results.

Review the individual test results, not just the event summary page: Review your graded PT results with your lab director. Document corrective action for scores below 100%. **Evaluate all ungraded results.**

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/EHSPHL/PHL/train.htm)

Basic Course in Urine Sediments

May 12	Shoreline
May 17-18	Shoreline

(6-hour evening course 3 hours each evening)

2005 WSSCLS/NWSSAMT Spring Meeting

April 21-23	Spokane

Northwest Medical Laboratory Symposium

October 26-29	Seattle

12th Annual Clinical Laboratory Conference

November 7	Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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